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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/386,591	08/31/1999	PHILIP NEEDLEMAN	MON-103.0C/ON	1579

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/386,591

Applicant(s)

Needleman

Examiner

Anne Marie Wehbé

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 16, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-7, 12, 13, and 22-47 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-7, 12, 13, and 22-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/16/02 has been entered. Applicant's submission of an IDS on 12/16/02 has also been entered. Claims 3-7, 12-13, and 22-47 are pending in the instant application. An action on the merits follows.

Please note that the Art Unit and Examiner of Record have changed, see page 6.

Those sections of Title 35, US code, not included in the instant action can be found in the previous office action.

Claim Rejections - 35 USC § 112

Claims 22-25, 27-28, 31, 33, 41, and 47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as claimed.

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Previous office actions, paper nos. 7 and 11, have properly analyzed the specification in accordance with the factors identified in *In re Wands*. The instant grounds of rejection states that the specification fails to provide sufficient guidance that the particular peptide sequences recited in the claims would function in a DNA vaccine as claimed. In particular, the previous office actions stated that the prior art teaches peptide vaccines incorporating these particular sequences and not DNA vaccines, citing Rittershaus and Thomas, and that success with peptide vaccines does not provide predictability of success with DNA vaccines based on the substantial differences between the administration of peptides and DNA encoding peptides to a mammal. The previous office actions supported these findings with evidence in the form of references by Eck and Wilson and Restifo et al. The previous office actions concluded that in the absence of sufficient guidance, the lack of working examples using the specified peptide sequences in the context of a DNA vaccine, the art recognized differences between the administration of peptides versus DNA, and the art recognized unpredictability of using DNA vaccines to treat or prevent disease, it would have required undue experimentation for the skilled artisan at the time of filing to make an use the invention as claimed.

The applicant has not provided any arguments regarding these grounds of rejection. Thus, the rejection of record stands for reasons of record as discussed in detail in paper nos. 7 and 11.

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Claim Rejections - 35 USC § 103

Claims 3, 6-7, 26, 29-20, 34-36, 40, and 42-46 are rejected under 35 U.S.C 103(a) as being unpatentable over Thomas et al. in view of Francis and Clarke. Paper no. 4, pages 3-4, under section 4 presents the instant grounds of rejection for the claims.

The applicant has not provided any arguments regarding these grounds of rejection. Therefore, the rejection of claims 3, 6-7, 26, 29-20, 34-36, 40, and 42-46 stands for reasons of record as discussed in detail in paper nos. 4, 7, and 11.

Claims 4-5 and 37-39 are rejected under 35 U.S.C 103(a) as being unpatentable over Thomas et al. in view of Francis and Clarke as applied to claims 3, 6-7, 26, 29-20, 34-36, 40, and 42-46 above, and further in view of Donnelly et al. Paper no. 4, pages 5-6, under section 6 presents the instant grounds of rejection for the claims.

The applicant has not provided any arguments regarding these grounds of rejection. Therefore, the rejection of claims 4-5 and 37-39 stands for reasons of record as discussed in detail in paper nos. 4, 7, and 11.

Claims 12-13 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. in view of Brown et al. Paper no. 4, page 6, section 7, presents the instant grounds of rejection for the claims.

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The applicant has not provided any arguments regarding these grounds of rejection. Therefore, the rejection of claims 12-13 and 32 stands for reasons of record as discussed in detail in paper nos. 4, 7, and 11.

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Fri from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D.
PRIMARY EXAMINER

